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*Regarding the applicant's traversal of the prior restriction requirement:*

The applicant respectfully disagrees with the Examiner's characterization that applicant had failed to traverse the prior restriction requirement. In the applicant's prior response, the applicant had expressly traversed the Examiner's restriction of the claims, pointing out that as (a) the present application has been filed as a 35 USC 371 application of PCT/GB03/03040 and (b) no objection to "unity of invention" to the slate of claims in the international application then presumptively the Examiner's lodging of a restriction requirement was improper. The nature of the application was expressly identified in the Application Data Sheet accompanying the application.

*Regarding the rejection of claims 1 – 20 under 35 USC 112, 2<sup>nd</sup> para.:*

The applicant's amendments to the claims entered in this paper are believed to fully address and overcome the Examiner's grounds of rejection. Accordingly reconsideration of the propriety of the rejection and its withdrawal is respectfully requested.

*Regarding the Examiner's objections to claim 2:*

The amendments to claim 2 entered in this paper are believed to fully address and overcome the Examiner's grounds of rejection. Accordingly reconsideration of the propriety of the rejection and its withdrawal is respectfully requested.

*Regarding the Examiner's rejection of claims 1, 2, 5-12 and 14-20 under 35 USC 103(a) in view of FR 2646352 A1 to Chicouri et al. (hereinafter FR '352):*

The applicant traverses the Examiner's rejection of the foregoing claim in view of the chi reference.

A review of the abstract of the Chicouri reference reveals that the Chicouri compositions are directed to: "The invention relates to novel pharmaceutical compositions intended for human or animal therapy. It relates to pharmaceutical compositions consisting of a mixture of extract rich in anthraquinone glucosides of vegetable origin, a mucilaginous extract consisting of psyllium and guar gum and an extract of Prunus, in combination or mixed with a pharmaceutically acceptable, non-toxic, inert excipient or vehicle. The

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pharmaceutical compositions according to the invention are used as a medicament for the treatment of constipation. “ *Prima facie*, the Chicouri compositions appears to be distinguishable being based on an apparent synergistic series of essential constituents which such system can be differentiated from the applicant’s presently claimed compositions.

Although the Examiner asserts at page 7 of the *Office Action*, that:

taught by Chicouri to provide the instantly claimed invention because Chicouri teaches that a surfactant having the claim-designated range of molecular weights, such as propylene glycol (propylène glycol), dipropylene glycol (dipropylène glycol) or trihydroxy propane, as well as polyoxyethylene-based surfactants, can be added to the active ingredients of the reference mixture in the making of an ingestible composition that is in a form so that in use it is dispersed in a liquid prior to ingestion. Chicouri further teaches that the amount of the surfactants added in the preparation of the reference composition should be in an amount such that it allows ingestion of the solution. See page 3, lines 1-22 and page 5, lines 1-10. At the time the invention was made, one of

the applicant disagrees with the Examiner’s reading of the relied-upon section of the Chicouri reference, which reads:

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Si la composition est une préparation liquide, on utilisera de préférence une solution ou suspension des principes actifs dans un solvant non polaire très visqueux comme le propylène glycol, le dipropylène glycol ou le trihydroxy propane. Des mélanges de solvants peuvent être envisagés, et il est utile d’y ajouter une

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quantité d’eau suffisante pour que la viscosité de la solution soit dans des zones qui permettent l’ingestion d’une solution.

The foregoing does not mention surfactants, but only mentions the possible utility of three types of organic *solvents*, viz., propylene glycol, dipropylene glycol and trihydroxy propane which may find use if the composition is in the form of a liquid, in order to provide an adjustment to the viscosity of the liquid and thus improve the ingestability of the Chicouri solution. Thus, Chicouri does not “teach” what the Examiner presupposes.

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No surfactants are taught by Chicouri at the above passage, and any reference to the three types of organic solvents are limited to liquid forms of the Chicouri compositions. Such does not appear to be relevant to granular delivery forms of the Chicouri compositions, but are limited to liquid delivery forms which are prepared and intended to be used as-supplied to a patient.

The Examiner's citation as to Chicouri at page 5, lines 1 -10 for the proposition that the surfactants provide for ingestion of the solution also appears to be flawed. That passage of Chicouri reads:

- 5 -

**EXEMPLE 4**

**Sachets de poudre**

5	. Extrait de feuilles de séné titrant 40 %	
	en sennosides .....	200 g
	. Gomme Guar micronisée .....	1000 g
	. Extrait sec de pruneaux .....	120 g
10	. Polymère d'oxyde d'éthylène et	
	d'oxyde de propylène .....	40 g
	(vendu sous la marque PLURONIC F.18)	
	. Cellulose microcristalline .....	2640 g

**pour 1000 sachets**

which very passage saliently omits, and excludes any reference to psyllium as a constituent but rather includes (respectively) sennoside extracts, guar gum, prune extracts, a polyoxyethylene/polyoxypropylene polymer (sold as Pluronic F18), and microcrystalline cellulose. Again, this reference to this composition according to Chicouri does not include any disclosure of an ingestible composition comprising isphagula (*Plantago psyllium*), colloidal silica, and an ingestible surfactant as clearly two of three primary and essential constituents of applicant's claimed invention, both isphagula and silica are absent. Furthermore, as pointed out above the Chicouri reference

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at best discusses the use of certain specific organic solvents as being useful in liquid preparations of compositions, but otherwise Chicouri is silent as to the utility of such organic solvents in other dosage forms. As to surfactants, the Chicouri reference provides no level of any intelligible "teaching" which regard to the presence of Pluronic F18, a "block-copolymer" comprising "blocks" surfactant in his Example 4 composition. The applicant asserts that in the absence of any demonstration of the utility of these materials in compositions proximate to those which the applicant presently claims, the Chicouri reference is appropriately dismissed from further consideration. Additionally the applicant also notes that in addition to the salient absence of isphagula and silica, the Ex. 4 composition of Chicouri includes a different set of essential constituents, viz., sennoside extracts, micronized guar gum, prune extracts, and the bulk of the composition, namely about 2/3 rds of the composition being microcrystalline cellulose. Thus, Chicouri clearly fails to both teach and/or suggest the presently claimed invention in any relevant manner.

It is the applicant's view that the Examiner's rejection of the claims is in no small part based on a "hindsight reconstruction" of the applicant's invention which is based on a retrospective assemblage of the applicant's claimed invention wherein there lacks an appropriate teaching or suggestion. Such is believed to be inappropriate. In *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992), the Federal Circuit stated:

"It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." (quoting *In re Fine*, 837 F.2d at 1075, 5 USPQ2d at 1600)

It is the applicant's view that the prior art documents cited by the Examiner fail to meet the proper burden of proof, and that the presently presented claims should be allowed.

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*Regarding the Examiner's rejection of claims 1 – 20 under 35 USC 103(a) over FR 2646352 A1 to Chicouri et al. further in view of US 6361799 B1 to Palkhiwala et al. (hereinafter "US'799):*

The applicant traverses the Examiner's rejection of the claim sin view of the Palkhiwala reference.

For the sake brevity, the applicant herein incorporates by reference the foregoing remarks made with respect to the Chicouri reference as being equally relevant to the current grounds of rejection.

It is the applicant's view the Examiner's additional reliance upon the Palkhiwala reference does not cure the defects of the Chicouri reference or render the currently presented claims obvious in view of these combined references.

The applicant disagrees with the Examiner's assertions at page 11 of the Office Action that:

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blending the bulking agent, surfactants and excipients, in Column 5, lines 8-28. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add a colloidal silica having the claim-designated physical properties and to add the claim-designated surfactant to the composition and method of making thereof taught by Chicouri to provide the instantly claimed invention because Palkhiwala teaches that the addition and continuous blending of an effective amount of surfactants, such as polyethylene glycol, polyoxyethylene monostearate, glycerol polyethylene glycol oxystearate, and a polyoxyethylene sorbitan fatty ester, as well as the addition of an effective amount of a colloidal silicon, such as AEROSIL® or AEROSIL 200®, having a particle size between 5nm and 5µm and a specific surface area of between 50 and 400gm<sup>-2</sup> with a bulking agent, such as the ingestible ispaghula or psyllium powder taught by Chicouri, provides for the making of a powder composition which is both readily dispersible in other granulated powders or a liquid such as water without clumping; moreover, like Chicouri, Palkhiwala teaches the desirability to obtain a psyllium composition that has improved

The applicant points out that the secondary Palkhiwala reference is useful only in supplementing that purported teaching of the primary Chicouri reference which as has been discussed previously fails to teach or suggest the specific composition as presently claimed by the applicant. However the consideration of the secondary reference necessarily inherits the limitations of the primary reference, in which case, the Palkhiwala reference at best might be considered as suggesting a process for the manner of producing the Chicouri reference compositions, but it is the applicant's view that such a consideration does not overcome the shortcomings of the Chicouri reference.

As has been noted previously, the Chicouri reference fails to disclose the utility of any surfactants in powdered or granular compositions, and the sole reference to a surfactant occurs in Chicouri's Example 4 composition which for no identified reason discusses the

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inclusion of the Pluronic F-18 block copolymer surfactant but does not specify any benefits or utility therefor. Thus, the Examiner's present reliance on the Palkhiwala reference to supplement the Chicouri reference as to the identity of other potentially useful surfactants which are unspecified in Chicouri does not overcome the other flaws of Chicouri, namely the requirement of a different series of essential constituents which are different than the essential series of the essential constituents of the applicant's presently claimed invention. Thus, the addition of the secondary reference to Palkhiwala must be read in conjunction with the teaching of Chicouri which can be either (i) differentiated as based on a different "system" of essential constituents as disclosed above, and (ii) fails in teaching or suggesting the utility of specific surfactants to provide the improved compositions which the present applicant provides. The Examiner's attention is directed to the latter parts of the applicant's specification as disclosing superior products formed according to the present applications' teachings which properties were unknown to the prior art, and in no way suggested by the prior art.

Accordingly in view of the foregoing, reconsideration of the propriety of the rejection in view of the combined Chicouri and Palkhiwala reference, and withdrawal of the current rejection of the claims is respectfully requested.

Should the Examiner in charge of this application believe that communication with the undersigned will favorably advance the prosecution of this application, they are invited to contact the undersigned at their convenience.

Petition for a Three-Month Extension of Time

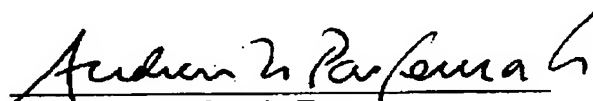
The applicants respectfully Petition for a three-month extension of time in order to permit for the timely entry of this response. The Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263 with respect to this Petition.

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Conditional Authorization for Fees

Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, including any necessary extension of time petition and fee, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

Respectfully Submitted;



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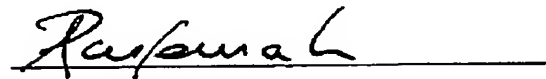
03 Feb. 2008

Date:

Tel: 212 808-0700

CERTIFICATION OF TELEFAX TRANSMISSION:

I hereby certify that this paper is being telefax transmitted to the US Patent and Trademark Office to telefax number: 571 273-8300 on the date shown below:



Andrew N. Parfomak

03 February 2008

Date:

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